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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/658,447

09/08/2003

Timothy Crowley

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EXAMINER

MENON, KRISHNAN S

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/658,447	Applicant(s) CROWLEY ET AL.	
	Examiner Krishnan S. Menon	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-111 is/are pending in the application.
- 4a) Of the above claim(s) 1-6,13-64 and 69-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-12,65-68 and 72-111 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1 and 3-111 are pending after the amendment of 4/7/08, of which claims 1-6,13-64, 69-71 are withdrawn from consideration. Claims 7,65,81,98 and 111 are independent.

Claim Rejections - 35 USC § 103

1. Claims 7-12, 65-68 and 72-111 are rejected under 35 U.S.C. 102(b) as unpatentable over Sundberg et al (US 6,090,251) and/or Ehrfeld et al (US 4,979,211) and/or Quake et al (US 2004/0248167) and/or Hillman et al (US 5,204,525).

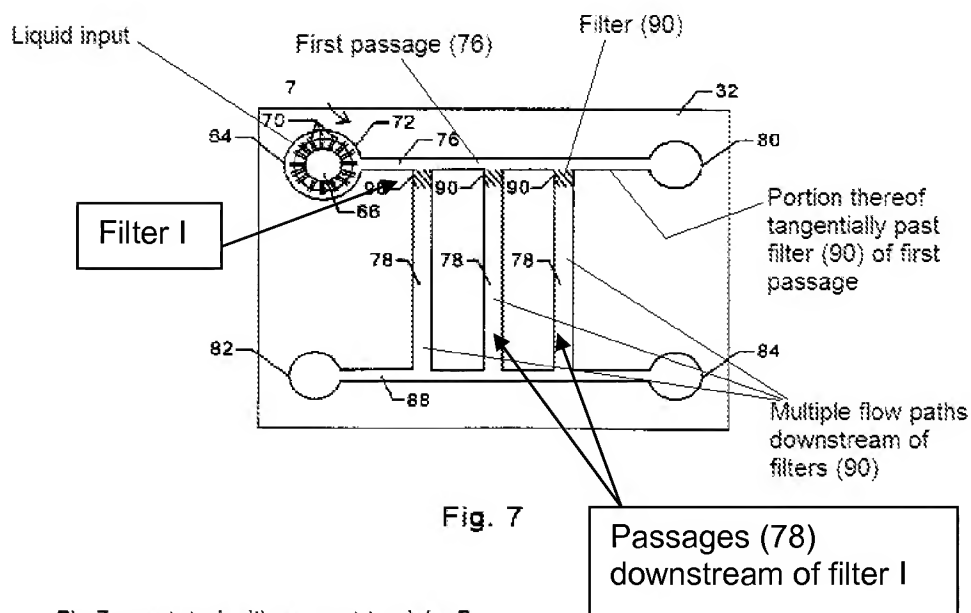


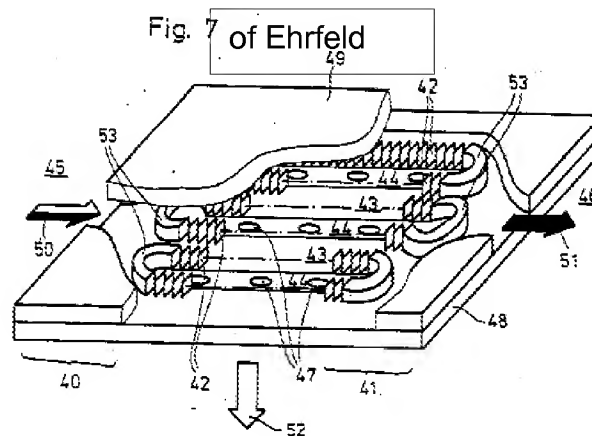
Fig 7 annotated with respect to claim 7.

Figure 7 of the reference is annotated with the elements of claim 7 to show how the claims read on the reference.

Sundberg teaches a microfluidic instrument in figure 7 comprising an input (70), a first passage (76), a tangential filter in the first passage (the first of the filter 90, which is a weir type filter – see figure 8), and multiple liquid flow paths (78) downstream of the filter as claimed: the subsequent channels (78) downstream of filter I (see figure above) read on this limitation, i.e, of the three channels (78) the second and third channels (78) are downstream and is tangentially past the first filter (90). Figure 7 shows only three channels 78, but the abstract and column 4 lines 3-10 teaches that any number of channels 78 are possible (such as five or more). All flow paths are parallel, lead to an output (82,84), have analytical provisions (column 1 lines 10-15, column 5 lines 15-28), and have capillary action (abstract). Tangential flow as in claim 85 over filter 90. Regarding “unfiltered liquid”, liquid in channel (76) would be “unfiltered” with respect to the liquid on the filtrate side of the filter.

Regarding the new limitation (introduced 4/7/08) of the filter on each side of the first passage, this would be only duplication of the Sundberg structure of filter 90 and channels 78 on the other side of passage 76, and it would be obvious to one of ordinary skill to do so to increase the filtration capacity or rate. Duplication of parts is not patentable unless a new and unexpected result is produced. In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

Ehrfeld teaches microfilters (42) straddling a first passage (50-51) having filtrate passages (47) as claimed – see figure 7 reproduced below:



It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Ehrfeld in the combination of references to increase the filtration capacity as can be understood from Ehrfeld.

With respect to having all the 'downstream capillary channels' in the first passage as downstream of all the filters, Hillman teaches capillary action pump having at least one capillary that can be used for pumping fluids (column 2, lines 50-60). Such capillary action pumps are also well known in the art (a forward and back search on the Hillman reference will show this). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching such as of Hillman in the combination of references or Sundberg for providing sufficient pumping forces for pumping the fluids through the filters. One would use the teaching of Hillman also because it affords constant flow rates without having to use additional means for flow control.

Claims 65-68, 98 recite the means plus function language for continuous flow, which is capillary action as disclosed in the specification (35 USC 112, sixth paragraph, means plus function language would be the corresponding disclosure or equivalents

thereof). Sundberg teaches the structure recited in the claims as above. With respect to claim 66, the plurality of parallel channels are defined to “draw the liquid filtrate therethrough”, which read on the channels 78 of the reference. This is also obvious from the teaching of Hillman.

Claim 87, 104: smooth surface, semiconductor – see materials in column 6 lines 57-67.

Claim 88, 101: several instruments, part of a device – see abstracts: microfluidic substrates; column 1 lines 5-10 describe the invention as structure for introduction of fluids into devices.

Claim 92: covering plate – see figures 7 and 8: plan and cross-sectional elevation, showing covered structures.

Claim 97: weir type opening – see figure 8.

Claim 72-80, 82,83, 89,90, 99,100, 107-110: the recitations in these claims, ‘the complex fluid’, blood, cell lysis, the flow times, filtrate quantities, and other ‘instrument requirements’ are intended use, which are not patentable. The instrument taught by the reference is capable of all these. See also column 9 lines 50-67.

Claim 102, 105: multiple receiving means – see 70, figure 7.

Claims 11 and 12 recite details of electro-optical means. Quake teaches a laser-optic detection system (figures, abstract, col 7 lines 50-59). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Quake in the

teaching of the combination of references for one of the various intended uses of the system for sample separation and analysis.

Claims 84,86,93-96 and 106 have further limitations of certain dimensions of the channels. Sundberg teaches how to size the channels and optimize the instrument in column 9 line 50-column 10 line 38. Moreover, In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. Also, Sundberg teaches channel widths, etc., in column 6 lines 9-25 with respect to the generation of capillary action. The length of the channels would depend of the filtration rate needed and the filter capacity, and can be optimized, or designed in. Quake teaches the length of the channels as about 1 μm to 2 cm, depending on the need for the analytical methods (see paragraph 187). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Quake in the teaching of the combination of references for analysis of the samples.

2. Claims 7-12, 65-68 and 72-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Brody (US 5,922,210) and/or Ehrfeld et al (US 4,979,211) and/or Quake et al (US 2004/0248167) and/or Hillman et al (US 5,204,525).

Brody teaches an instrument comprising an input (1-figures), filter (5), passages from input to filter (4) and filter to output (6) all of which are capillary flow paths (inherent), and liquids flow by capillary action (inherent). Material is silicon wafers (example). Channel dimensions, separated particle sizes and fluid volumes – see column 3 lines 50-67, column 5 lines 4-25 and col 6 lines 13-25. the fluid to be treated, such as blood, and residence times (15 seconds), are intended use.

Regarding the limitation “filter located along each side of the first passage”, Brody shows only a filter on one side of the passage. However, providing filter and filtrate passage on both sides of the first passage would be an obvious duplication of those parts in a mirror image in the structure of Brody, and would be obvious to one of ordinary skill.

Ehrfeld teaches microfilters (42) straddling a first passage (50-51) having filtrate passages (47) as claimed – see figure 7 reproduced above:

Instant claims add the further limitation of plurality of fluid flow paths connected to the first passage to receive flow therefrom by capillary action and channel dimensions, which Brody does not teach. Quake teaches plurality of capillary flow paths (32) from a reservoir (48) (see - figure 1) which lead to an analyzer (50), and electro-optical means for testing (abstract); and channel dimensions such as length, width, etc in paragraph 153 and 187. It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Quake in the teaching of Brody and/or Ehrfeld for the analysis of the filtered samples as taught by Brody or applications such as taught by

Ehrfeld, for analysis such as DNA detection as taught by Quake. One of ordinary skill in the art would also use the teaching of Brody or Ehrfeld to pre-filter the samples of Quake as taught by Brody for removing unwanted particulates.

Hillman teaches capillary action pump having at least one capillary that can be used for pumping fluids (column 2, lines 50-60). Such capillary action pumps are also well known in the art (a forward and back search on the Hillman reference will show this). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching such as of Hillman with the teaching of the other references for providing sufficient pumping forces for pumping the fluids through the filters, because Brody teaches that 'surface tension forces' can be used for such pumping. One would use the teaching of Hillman also because it affords constant flow rates without having to use additional means for flow control.

Response to Arguments

Applicant's arguments filed 4/7/08 have been fully considered but they are not persuasive. They are addressed in the rejection. Claim 111 is not patentable without specific features unique to applicant's invention.

Allowable Subject Matter

The following independent claim drafted by the examiner and considered to distinguish patentably over the art of record in this application, is presented to applicant for consideration:

(New) An instrument for observation, treatment or analysis of a drop-size sample of a liquid comprising:

a liquid input opening for receiving the sample,

a first passage leading from the liquid input opening to an expanded liquid flow region,

at least one weir filter located tangentially along each side of the first passage between the input opening and the expanded region,

a filtrate channel located on each side of the first passage parallel to the first passage,

each weir filter in communication with the first passage and the filtrate channel located on the same side of the first passage as the weir filter, and

the expanded region comprising a plurality of parallel capillary channels sized to sustain the draw of sample through the first passage tangentially past the weir filters by capillary action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on 571-272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Krishnan S Menon/
Primary Examiner, Art Unit 1797